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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,169	11/16/2005	Reinhard Nubbemeyer	SCH-1947-02	3554

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EXAMINER	
CHUI, MEI PING	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
04/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,169	NUBBEMEYER ET AL.	
	Examiner	Art Unit	
	MEI-PING CHUI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *n/a*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Receipt of Amendments/Remarks filed on 12/29/2008 is acknowledged. Claims 1-12 have been amended and new claims 13-16 are added in this application.

Upon further consideration, Applicants' amendments necessitated new ground(s) of rejection presented in this Office Action. Accordingly, this action is made **FINAL**.

Priority

Acknowledgment is made of Applicants' claim for foreign priority based on an application filed in Germany on 07/25/2002. However, it is noted that Applicants have not filed a certified copy of the English translation of the foreign application No. 10234525.2 as required by 35 U.S.C. 119(b).

Status of Claims

Newly submitted claims 13-16 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original claims 1-12 are drawn to a statutory **"composition of matter"**, and the new claims 13-16 are drawn to a statutory **"process"** (a method of male contraception).

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, claims **1-12** are presented for examination on the merits for patentability as they read upon the elected subject matter and claims **13-16** directed to non-elected invention are withdrawn.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

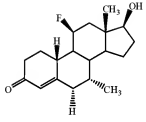
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

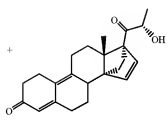
Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohlmann et al. (WO 02/059139) in view of Krattenmacher et al. (Canadian Patent No. 2208605).

Applicants Claim

Applicants claim a composition comprising: **(i)** an androgen, i.e. 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one (as structure **A** below), in combination with **(ii)** a gestagen, i.e. (21S)-21-hydroxy-21-methyl-(4, 17-ethano-19-norpregna-4,9,15-trien-3,20-dion (as structure **B** below), which the composition further comprises a pharmaceutically compatible vehicle and/or adjuvant:



A



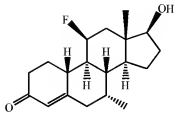
B

Determination of the scope and content of the prior art

(MPEP 2141.01)

Bohlmann et al. teach a composition comprising an androgenic 11β-halogen steroid, which is used for the preparation of a pharmaceutical composition for male menopause or male birth control therapy (also known as male contraceptive) (page 1: lines 1-11 and all structures in pages 5-11).

Bohlmann et al. teach that the 11β-halogen androgen steroid is 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one having the structure as below (page 14: lines 15-16 and Figure 1: compound I):



Bohlmann et al. also teach that the androgenic steroid, i.e. 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one, can be prepared with at least one pharmaceutical compatible vehicle and other adjuvants, i.e. surfactants, lubricants, fillers, for examples (page 11: lines 19-21 and page 21: lines 17-24), and can be administered orally, parenterally or percutaneously (where percutaneous is commonly also referred as transdermal) (page 20: lines 16-19). Bohlmann et al. further teach that the androgenic steroid can be used in combination with a progestogen to control male fertility (page 2, lines 5-7 and page 13, lines 3-16).

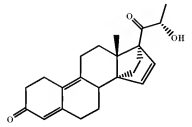
Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

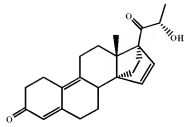
Bohlmann et al. suggest the androgenic 11β-halogen steroid can be used in combination with a progestogen for the preparation of male birth control therapy; however, Bohlmann et al. do not exemplify a specific progestogen. The deficiency is cured by the teaching of Krattenmacher et al.

Krattenmacher et al. teach a 14, 17-C_2-bridged steroid of formula (I) that has a good gestagen action. More specifically, Krattenmacher et al. teach the gestagen of formula (I) is

(21S)-21-hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9,15-triene-3, 20-dione (page 7, lines 22-23 and the structure as below). It is noted that the gestagen, taught by Krattenmacher et al., has the same structure as the claimed gestagen compound B set forth above):



the claimed gestagen (compound B)



(21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4,9,15-triene-3,20-dione (Krattenmacher et al.)

Krattenmacher et al. also teach that the gestagen compound can be used alone or in combination with other steroids in preparations for contraception use (page 9: lines 19-21).

Krattenmacher et al. further teach a pharmaceutical formulation comprising pharmaceutical vehicles, diluents, based on said gestagen compound, can be made and can be administered orally, or through a transdermal system, or transdermally (page 11: lines 8-14 and page 12: lines 1-3).

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teaching of Bohlmann et al. and Krattenmacher et al. to arrive at the instant invention.

One of ordinary skill would have been motivated to do this because it is known in the art that an androgenic 11β-halogen steroid, i.e. 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one, has been used for the preparation of a pharmaceutical composition for male menopause or male

birth control therapy and it is also taught in the art that the androgenic steroid can combine with a progestogen for controlling male fertility. Furthermore, the prior art, namely Krattenmacher et al., teach the compound: (21S)-21-hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9,15-triene-3, 20-dione has good gestagen action and can be used alone, or in combination with steroids, for the preparation of contraception medicaments. Therefore, the Examiner can only conclude that it would have been obvious to utilize an androgenic 11β-halogen steroid in combination with a gestagen to produce an effective pharmaceutical composition for reducing spermatogenesis and controlling male fertility, as taught by Bohlmann et al. and Krattenmacher et al.

From the teaching of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The previous rejection with respect to claims 1-12, under 35 U.S.C. 103(a) as being unpatentable over Bohlmann et al. (WO 02/059139) in view of Krattenmacher et al. (Canadian Patent No. 2208605), is maintained.

Response to Arguments

Applicants' arguments filed on 12/29/2008 have been fully considered but they are not persuasive.

Applicants argue that even each of the steroid components, as taught by Bohlmann et al. and Krattenmacher et al., of the composition would work for the same use, more is needed to

provide sufficient reason to make the particular claimed combination and the basis for the reason to combine the references (see Remarks: page 11).

The argument is not persuasive because each of the claimed components (the androgenic 11β-halogen steroid, i.e. 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one taught by Bohlmann et al., and the gestagen, i.e. (21S)-21-hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9,15-triene-3, 20-dione as taught by Krattenmacher et al.) are known and has been taught by the prior art of record. The prior art, namely Bohlmann et al., clearly teach the androgenic 11β-halogen steroid (e.g. 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one) is effective for reducing spermatogenesis and controlling male fertility, as well as for treating male menopause. The prior art also clearly suggests that the androgenic 11β-halogen steroid can be used in combination with a progestogen for preparing pharmaceutical compositions for male menopause or male birth control therapy. The secondary prior art, namely Krattenmacher et al., also clearly teach that the gestagen (21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9, 15-triene-3, 20-dione is an effective gestagen, and can be used in combination with other steroids to produce contraception medicament. Since both prior art clearly teach and suggest the use of the androgenic 11β-halogen steroid and the gestagen (21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9, 15-triene-3, 20-dione for the utility of male contraceptive medicament; hence, Applicants' argument by merely stating "more is needed to provide sufficient reason to make the particular claimed combination and the basis for the reason to combine the references" is not the kind of factual evidence that is required to rebut a prima facie case of obviousness, and thus cannot take the place of evidence in the record.

New Grounds of Claim Rejection

Claim Rejection - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

(1) Claim 5 is indefinite because it recites a male contraceptive agent, which is a combination of an androgenic 11β-halogen steroid of formula (I) and a gestagen. The general accepted plain meaning of the term "agent" usually refers as a single compound. Since the specification does not provide any definition for this term, it is unclear whether Applicants intend to claim a single compound or intend to claim a composition containing an androgenic 11β-halogen steroid of formula (I) and a gestagen. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, and thus rendering the claim indefinite.

In addition, claim 5 recites a combination of an androgenic 11β-halogen steroid of formula (I) and a gestagen without reciting a transitional phrase. Since a transitional phrase in a claim defines the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim; hence, in the absence of a transitional phrase, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, and the claim is, therefore, rendered indefinite.

(2) Claims 7 and 8 recite the limitations where "the androgenic compound of formula I is formulated pharmaceutically" (claim 7) or "the androgenic compound of formula I is provided for oral administration" (claim 8), according to claim 5. Since the independent claim 5 recites a combination of an androgenic compound of formula I and a gestagen, it is unclear whether the androgenic component is formulated pharmaceutically and provided as an oral formulation together with the gestagen component, or the androgenic component is formulated without the gestagen. Therefore, the claims are rendered indefinite.

(3) Claims 9-12 recite the limitations where "the gestagen is formulated pharmaceutically" (claims 9-10) or "the gestagen is suitable for oral, or transdermal, administration" (claims 11-12). Since its independent claim 5 recites a combination of an androgenic compound of formula I and a gestagen, it is unclear whether the gestagen component is formulated pharmaceutically and provided as an oral, or transdermal, formulation together with the androgenic compound of formula I, or the gestagen component is formulated without the androgenic compound of formula I. Therefore, the claims are rendered indefinite.

Notes to the Applicants

Claims 7 and 9-11 recite the phrases "such that" and "suitable for" are an optional language and does not constitute a positive recitation in the claims. The subject matter of a properly construed claim is defined by the terms that limit its scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. Since the prior art and the invention as claimed comprise the same components, and are not structurally distinguishable. In order to be limiting, the intended use must create a structural difference between the claimed

composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Therefore, for the examination purpose, it is the examiner's position to interpret that the composition can be released over an extended period the same as the composition taught in the prior arts set forth above.

Conclusion

No claims are allowed.

Applicants' amendments necessitated the new grounds of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. C./
Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616